DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

"Human Tissue Research: NIH Policies and Practices"

House Energy and Commerce Subcommittee on Oversight and Investigations

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June 13, 2006

Mr. Chairman and Members of the Committee:

My name is Dr. Susan Molchan, from the National Institute on Aging (NIA) at the National Institutes of Health (NIH), where I have worked since 2001 as a program director for clinical studies on Alzheimer's disease. I serve as a medical officer in the U.S. Public Health Service. Thank you for this opportunity to participate today.

I have been asked to address my experience with human tissue samples at the National Institute of Mental Health (NIMH), where I worked for nine years. I will address my experience specifically with one type of especially precious sample—spinal fluid— that I collected from a number of patients with Alzheimer's disease (AD) and volunteers in the early 1990s.

As a young scientist at NIMH, I conceived and conducted a study that now has implications for AD research. In the process of my research, I obtained very valuable material—spinal fluid. These human samples can be obtained only with the consent and understanding of each and every patient. Those who participate in our research trust that their fluid specimens will be handled carefully. As scientists, we carefully document and store this material.

As a doctor, my very first obligation is to advocate for the well-being and intentions of the patients who put their trust in me. Some of these patients had contributed their time and bodies to a number of my research studies and others at the NIMH. These good people were always ready to help in work on AD in any way my colleagues and I asked.

While at NIMH, a redirection of the program occurred and the new goals made it impossible for me to continue my work. Lack of support was intense for this project and I was not encouraged to stay. I went to work at the FDA for a few years, until 2001, when I was recruited to my current position as a program officer at NIA, where I work with AD scientists throughout the country.

In 2004, the university scientists who are the leaders of the NIA's clinical trials consortium, which serves as the primary mechanism through which NIH funds studies on the treatment of AD, proposed a study very similar to the one I had done at the NIMH. Several of my esteemed colleagues pressed me to obtain the samples I had collected. Such samples can be stored in freezers for years, and my colleagues and I had every reason to believe that they would still be available.

As research on AD has progressed, the need for spinal fluid samples has increased, as they may shed light on treatment options for this increasingly prevalent and devastating disease. All available scientific resources are needed to fight AD.

The head of the branch where I had worked at NIMH located and sent a small sub-set (**one cc** per individual participant of the approximately **50 cc** that I'd collected from each) of the spinal fluid samples to a university colleague for analyses (tests that were covered on the consent form under which study participants allowed me to collect their samples).

Twenty-five people had participated in the study as documented on a Continuing Review memo to the NIMH IRB, dated July 1, 1993. Although I hadn't collected spinal fluid on all of them, I had collected it on more than the 8 AD patients and two volunteers on whom fluid was located. The individual responsible for the samples at the NIMH emailed

me that some of the samples had been lost in “freezer thaw problems.” A request to inspect the freezers to hopefully find some samples was denied.

By the end of January, 2005 intriguing data resulted from analyses of the spinal fluid samples that we were able to recover. Incomplete as it was, it contributed to the success of a grant proposal that shows promise in advancing knowledge on the mechanisms and treatment of AD.

Several colleagues agreed the data from these samples were worth publishing in a scientific journal. These senior AD researchers pressed me for an answer as to why only a small amount of fluid was available, and on only a subset of the participants. This would need to be explained in any scientific submission of the data.

Since Congress has shown an interest in this matter, some progress has been made. I thank you for your interest in human tissue specimens that are so important to public health research.